



**DEPARTMENT OF DEFENSE**

**BILLING CODE 5001-06**

**Office of the Secretary**

**DOD-2011-HA-0085**

**RIN 0720-AB54**

**32 CFR Part 199**

**TRICARE; Removal of the Prohibition to Use Addictive Drugs in the Maintenance Treatment of Substance Dependence in TRICARE Beneficiaries**

**AGENCY:** Office of the Secretary, Department of Defense

**ACTION:** Proposed rule

**SUMMARY:** This rule proposes revisions to remove the exclusion of drug abuse maintenance programs and allow as part of a comprehensive treatment plan for an individual with substance dependence, the substitution of a therapeutic drug with addictive potential for a drug of addiction (e.g. the substitution of methadone for heroin). The current regulation prohibits drug maintenance programs where one addictive substance is substituted for another. However, this prohibition of maintenance treatment of substance dependence utilizing a specific category of psychoactive agent is outdated and fails to recognize the accumulated medical evidence supporting certain maintenance programs as one component of the continuum of care necessary for the effective treatment of substance dependence. Current medical evidence shows that this is medically or psychologically necessary and integral to the safe and effective treatment of drug abuse as is generally required for all treatment benefits for inclusion in the TRICARE benefit.

**DATES:** Written comments received at the address indicated below by [insert 60 days after publication of proposed rule in the Federal Register] will be accepted.

**ADDRESSES:** You may submit comments, identified by docket number and or Regulatory Information Number (RIN) number and title, by either of the following methods:

- Federal eRulemaking Portal: *www.regulations.gov*. Follow the instructions for submitting comments.
- Mail: Federal Docket Management System Office, 1160 Defense Pentagon, OSD Mailroom 3C843, Washington, DC 20301-1160.

*Instructions:* All submissions received must include the agency name and docket number or RIN for this Federal Register document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

**FOR FURTHER INFORMATION CONTACT:** CAPT Robert DeMartino, TRICARE Management Activity, Office of the Chief Medical Officer, telephone (703) 681-0070.

**SUPPLEMENTARY INFORMATION:**

Contingency operations involving DoD personnel are now in their tenth year. The advances in battlefield injury protection and medicine have drastically reduced the number of battlefield deaths and have returned our Service members home, injured, but prepared to recover. For many, pain related to injuries must be treated for many months and such long-term use of pain medications has put our Service members using those medicines at risk for dependence. This reality makes it ever more important to ensure that all safe and effective treatments for substance dependence are available to our Service members.

The current TRICARE regulation prohibits drug maintenance programs where a therapeutic drug with addictive potential is substituted for a drug of addiction. However,

medicine is constantly evolving including in the area of drug addiction treatments. In the past, there was not sufficient reliable evidence as that term is used in the TRICARE regulations at 32 CFR 199.4(g)(15), to establish that the substitution of one addictive drug for another was an effective part of a drug treatment program.

The changes proposed to the CFR will remove the specific prohibition on coverage of drug maintenance programs when one addictive drug is substituted for another, thereby allowing treatment regimens involving the substitution of one addictive drug for another when it is a medical necessity and appropriate for an individual beneficiary.

## **Regulatory Procedures**

### **Executive Order 12866 and Executive Order 13563**

Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated a "significant regulatory action" although not economically significant, under section 3(f) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget.

### **Public Law 104-4, Section 202, “Unfunded Mandates Reform Act”**

Section 202 of Public Law 104-4, “Unfunded Mandates Reform Act,” requires that an analysis be performed to determine whether any federal mandate may result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector of \$100 million in any one year. It has been certified that this proposed rule does not contain a Federal mandate

that may result in the expenditure by State, local and tribal governments, in aggregate, or by the private sector, of \$100 million or more in any one year, and thus this proposed rule is not subject to this requirement.

**Public Law 96-354, “Regulatory Flexibility Act” (RFA) (5 U.S.C. 601)**

Public Law 96-354, “Regulatory Flexibility Act” (RFA) (5 U.S.C. 601), requires that each Federal agency prepare a regulatory flexibility analysis when the agency issues a regulation which would have a significant impact on a substantial number of small entities. This proposed rule is not an economically significant regulatory action, and it has been certified that it will not have a significant impact on a substantial number of small entities. Therefore, this proposed rule is not subject to the requirements of the RFA.

**Public Law 96-511, “Paperwork Reduction Act” (44 U.S.C. Chapter 35)**

This rule does not contain a “collection of information” requirement, and will not impose additional information collection requirements on the public under Public Law 96-511, “Paperwork Reduction Act” (44 U.S.C. Chapter 35).

**Executive Order 13132, “Federalism”**

E.O. 13132, “Federalism,” requires that an impact analysis be performed to determine whether the rule has federalism implications that would have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. It has been certified that this proposed rule does not have federalism implications, as set forth in E.O. 13132.

**List of Subjects in 32 CFR Part 199**

Claims, Dental health, Health care, Health insurance, Individuals with disabilities, Military personnel.

Accordingly, 32 CFR Part 199 is proposed to be amended as follows:

PART 199 – [AMENDED]

1. The authority citation for Part 199 continues to read as follows:

Authority: 5 U.S.C. 301; 10 U.S.C. chapter 55.

2. Section 199.4 is amended by revising paragraph (e)(11) introductory text, and removing and reserving paragraph (e)(11)(ii), to read as follows:

**§ 199.4 Basic program benefits.**

\* \* \* \* \*

(e) \* \* \*

(11) Drug abuse. Under the Basic Program, benefits may be extended for medically necessary prescription drugs required in the treatment of an illness or injury or in connection with maternity care (refer to paragraph (d) of this section). However, CHAMPUS benefits cannot be authorized to support or maintain an existing or potential drug abuse situation whether or not the drugs (under other circumstances) are eligible for benefit consideration and whether or not obtained by legal means. Drugs, including addictive drugs, prescribed to beneficiaries undergoing medically supervised treatment for a substance use disorder are not considered to be in support of, or to maintain, an existing or potential drug abuse situation and are allowed. The Director, TRICARE Management Activity may prescribe appropriate policies to implement this prescription drug benefit for those undergoing medically supervised treatment for a substance use disorder.

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(ii) [Reserved]

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Dated: December 21, 2011.

Aaron Siegel,  
Alternate OSD Federal Register Liaison Officer,  
Department of Defense.

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